

Radiofrequency Ablation Versus Bipolar Electrocautery for the Treatment of Nasal Obstruction in Obstructive Sleep Apnea Patients Using Continuous Positive Airway Pressure

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Received 14 February 2020 • Revised 13 April 2020 • Accepted 30 April 2020 • Published online 1 July 2020

Abstract:

Objective: To investigate the treatment effect of radiofrequency ablation (RFA) on nasal obstruction, continuous positive airway pressure (CPAP) compliance, Epworth sleepiness scale (ESS) and sleep quality were compared with that of bipolar electrocautery (BEC) in patients using CPAP.

Material and Methods: Participants were randomised into two groups and treated with either RFA or BEC. Data were collected regarding nasal obstruction, total nasal symptoms, CPAP compliance, daytime sleepiness and sleep quality before and after treatment at 1, 3 and 6 months.

Results: Twenty-eight patients were enrolled in the study. Both methods relieved nasal obstruction at 1, 3 and 6 months. At 6 months, the symptom was improved by 83.4% and 64.2% in the RFA and BEC groups, respectively. The total nasal symptoms decreased at 3 and 6 months in both groups as well, exhibiting 75.7% and 40.6% improvement at 6 months in the RFA and BEC groups, respectively.

Conclusion: Both RFA and BEC have the ability to relieve nasal obstruction in such patients.

Keywords: bipolar electrocautery, CPAP, nasal obstruction, obstructive sleep apnoea, radiofrequency ablation

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J Health Sci Med Res 2020;38(4):297-305
doi: 10.31584/jhsmr.2020749
www.jhsmr.org

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Introduction

Obstructive sleep apnoea (OSA) is a sleep disorder that leads to sleep disturbance and excessive daytime sleepiness.^{1,2} It also affects patients' work and quality of life and increases the risk of cardiovascular consequences.³⁻⁷ Continuous positive airway pressure (CPAP) is the primary treatment for moderate to severe OSA.^{8,9} Nasal obstruction is one of the most common symptoms complained about during CPAP use and is usually caused by hypertrophy of the inferior turbinate.¹⁰⁻¹² This side effect often causes patient discomfort when using CPAP, leading to poor compliance and, eventually, abandonment of the therapy.¹³⁻¹⁵ Conservative medical therapies, such as nasal steroids and decongestants, are not always effective in controlling turbinate hypertrophy in these patients.¹⁶⁻¹⁸ Recently, a systemic review and meta-analytic study did not confirm the benefits of topical nasal steroid on CPAP compliance in OSA patients.¹⁹ Therefore, surgical treatments for turbinate tissue shrinkage should be considered in such patients with medical failure.²⁰⁻²² Among these surgical methods, the minimally invasive procedures, including electrocautery and radiofrequency ablation (RFA), are preferred because they reduce tissue volume while preserving mucosal epithelial function, causing minimal complications.²³ Thus, this study was designed to investigate the treatment effect of RFA on nasal congestion compared with that of bipolar electrocautery (BEC) in patients using CPAP. Furthermore, we assessed the impact of total nasal symptoms, peak nasal inspiratory flow (PNIF), CPAP compliance, CPAP attitude, postoperative pain score and sleep quality after treatment.

Material and Methods

A prospective, randomised, single-blind study was performed at the snoring clinic of Otolaryngology Outpatient Department and the operating room of Songklanagarind

Hospital from January 2016 to May 2019. The study protocol was approved by the Human Research Ethics Committee, Faculty of Medicine, Prince of Songkla University, and informed consent was obtained from each patient. Adult OSA patients using fixed pressure CPAP for at least 3 months who had symptoms of nasal obstruction via a visual analogue scale of >5 and bilateral inferior turbinate hypertrophy of grades 2-3 via the Friedman grading system²³ were enrolled. Patients with previous nasal or sinus surgery, septal deformity, nasal polyposis, sinusitis, nasal cavity tumour or coagulation disorder were excluded. All patients stopped using nasal or systemic steroids for at least 2 weeks, and no decongestants or antihistamine were taken within 1 week before surgery.

The patients were randomly assigned into two groups (Groups A and B) by block of four randomisation. The RFA treatment was applied in Group A, and the BEC treatment was applied in Group B. An investigator prepared the setting machine behind the partition screen and patients were blinded to which type of energy was used. The same reusable bipolar tip (Bipolar RaVoR™ needle electrode, Sutter Medizintechnik GMBH, Freiburg, Germany) was used in both groups. The surgical procedure was performed by a single otolaryngologist (K.T.) who was unblinded to the treatment group. Another unblinded otolaryngologist (W.S.) examined all patients before and after treatment.

The procedures were performed in an operating room under local anaesthesia. A cotton pledget soaked in 4.0% xylocaine solution was placed into each inferior turbinate. After 5 minutes, under a nasal telescope, 1.0% lidocaine hydrochloride 40 mg/2 mL for 2 mL was infiltrated at the anterior end of the inferior turbinate. Then, the surgeon inserted the active portion of a bipolar needle electrode under visualisation into the submucosa of the anterior part of the inferior turbinate. The RFA was

performed using a Quantum Molecular Resonance generator (Quantum; Telea Electronic Engineering, Sandrigo, Italy) with an energy of 4 megahertz. For the BEC, an energy of 20 watt was delivered by an Electrosurgical unit (ERBE ICC-350; Erbe Elektromedizin GmbH, Tübingen, Germany). Immediate nasal packing was applied postoperatively for both procedures. All patients were observed carefully for 30 minutes and allowed to be discharged with home medication, including oral antibiotics (Amoxicillin 2 gram/day or Azithromycin 500 mg/day for penicillin allergy) for 7 days, rescue medications for pain (acetaminophen) and oral decongestants (pseudoephedrine). Topical nasal steroid or antihistamine medication was not allowed during the study.

All patients were evaluated regarding their total nasal symptoms, endoscopic inferior turbinate grading, PNIF, CPAP compliance, Epworth sleepiness scale (ESS) and sleep quality measured by the Functional Outcomes of Sleep Questionnaire (FOSQ) preoperatively, at 1, 3 and 6 months after surgery. Moreover, the pain scores and surgical complications were assessed both immediately and 2 weeks after surgery. The nasal symptoms were assessed by using visual analogue scale (VAS), a 10-cm scale that ranges from no symptoms to worst symptom for each of the symptoms including nasal obstruction, rhinorrhea, nasal itching, sneezing, sense of smell, cough, eye itching, postnasal drip and sinonasal pain. The total nasal symptom score was the sum of scores for all nasal symptoms. Inferior turbinate was graded by nasal endoscopy according to the Friedman grading system.²⁴ Grade I was defined as mild enlargement without obvious obstruction. Grade II was in between grade I and III. For grade III, the turbinate completely occluded the nasal cavity. PNIF was used to assess the severity of nasal obstruction by measuring the volume of nasal airflow (L/min) using the In-Check portable inspiratory flow meter (Clement Clarke International Ltd., Harlow, United Kingdom).

Patients were asked to exhale and then inhale through the nose three times and the maximum value among three values was chosen as the PNIF. CPAP compliance was measured by self-reported diary records of nightly CPAP use. Good CPAP compliance is usually defined as at least 4 hours of nightly use for 70.0% of the nights.^{8,9} The ESS is a set of self-reported questionnaires that measures the degree of daytime sleepiness in eight common situations.²⁵ An ESS score greater than 10 is generally considered excessively sleepy. The sleep quality was measured by the Thai version of FOSQ.²⁶ This is a set of self-administered questionnaires consisted of 30 items focusing on five domains including general productivity, vigilance, social outcome, activity level, and sexual relationship. Each item is scored on a 4-point likert scale in which the lower score means more dysfunction of quality of life. The attitude and ease of CPAP use were measured by 10-cm VAS scale ranging from easiest to most difficult. The total score can range from 0 to 24 in which a lower score means less sleepiness.

Statistical analysis was conducted using the EpiData software (version 3.1) and R software (version 3.5.1). The baseline data were reported as numbers (percentage), means (standard deviation) or medians (interquartile range). Comparison between the groups was performed via the chi-squared test or Fisher's exact test for nominal variables and the Wilcoxon-Mann-Whitney U test for ordinal variables. The generalised estimating equation model was used to compare data within the same groups at before and 1, 3, 6 months after surgery. A p-value of less than 0.05 was considered statistically significant.

Results

All patients who entered the protocol (n=28) completed the study. Subjects were divided into two groups of 14 patients each. The mean age was 52.8±9.7

years in the RFA group and 51.9±12.2 years in the BEC group. The average body mass index (BMI) was 28.9±3.8 kg/m² in the RFA group compared with 27.3±3.3 kg/m² in the BEC group. The severity of OSA and the characteristics of CPAP usage were not significantly different between the groups (Table 1). Moreover, the baseline nasal symptoms, PNIF, ESS and FOSQ were almost similar in both groups.

Nasal obstruction in both groups postoperatively decreased significantly at 1, 3 and 6 months consecutively (p-value<0.001). Additionally, there was no statistically significant difference between the two groups (Table 2). At 6 months post-surgery, nasal obstruction improved by 83.4% and 64.2% in the RFA and BEC groups, respectively. In the RFA group, there were higher baseline total nasal symptoms scores than in the BEC group. However, these scores reduced significantly after 1, 3 and

6 months in the RFA group (p-value<0.001, p-value<0.001, p-value<0.001) compared with after 3 and 6 months in the BEC group (p-value<0.05, p-value<0.05), without a statistical difference between the groups (Table 2). There was an overall 75.7% and 40.6% improvement in the total nasal symptom scores in the RFA and BEC groups, respectively. The symptoms of rhinorrhoea, sneezing, coughing and itchy nose improved significantly at 1, 3 and 6 months postoperation in the RFA group. The symptoms of itchy eyes, anosmia and facial pain did not exhibit significant changes before or after treatment in either group.

The PNIF increased significantly at 1, 3 and 6 months in the RFA group (p-value=0.005, p-value=0.001, p-value=0.008) compared with at 3 and 6 months in the BEC group (p-value=0.022, p-value=0.002), without a significant difference between the groups. The inferior

Table 1 Demographic characteristics of participants (n=28)

Characteristics	RFA (n=14)	BEC (n=14)	p-value
Age (years), mean (S.D.)	52.8 (9.7)	51.9 (12.2)	0.773
Gender, n (%)			0.385
Male	9 (64.3)	12 (85.7)	
Female	5 (35.7)	2 (14.3)	
BMI (kg/m ²), mean (S.D.)	28.9 (3.8)	27.3 (3.3)	0.232
Underlying disease, n (%)			1.000
Hypertension	9 (64.3)	5 (35.7)	
Diabetes mellitus	4 (28.6)	2 (14.3)	
Allergy	7 (50.0)	4 (28.6)	
Dyslipidaemia	6 (42.9)	6 (42.9)	
Severity of OSA (events/h), n (%)			0.695
Mild	1 (7.1)	0 (0)	
Moderate	5 (35.7)	4 (28.6)	
Severe	4 (28.6)	10 (71.4)	
CPAP pressure (cmH ₂ O), mean (S.D.)	8.8 (2.1)	7.8 (1.9)	0.216
Inferior turbinate grading, n (%)			0.678
Grade 2	3 (21.4)	5 (35.7)	
Grade 3	11 (78.6)	9 (64.3)	

BMI=body mass index, OSA=obstructive sleep apnoea, CPAP=continuous positive airway pressure, RFA=radiofrequency ablation, BEC=bipolar electrocautery, S.D.=standard deviation, cmH₂O=centimetres of water, kg/m²=kilogram per meter squared

turbinate grading was reduced at 1, 3 and 6 months in both groups (p -value <0.001). In the RFA group, the ESS scores decreased significantly at 1, 3 and 6 months postoperation compared with at 6 months in the BEC group. However, the FOSQ did not change pre- or postoperatively in either group (Table 3).

Table 2 Comparison of the nasal obstruction and total nasal symptoms at baseline, 1, 3 and 6 months after treatment

Symptoms	Pre-treatment	1 month	3 months	6 months
Nasal obstruction, mean (S.D.)				
RFA	6.5 (1.5)	2.2 (1.0)**	1.4 (0.9)**	1.4 (1.4)**
BEC	5.9 (1.0)	2.5 (2.3)**	1.8 (1.9)**	1.9 (1.6)**
p-value	0.231	0.586	0.565	0.348
Total nasal symptoms, mean (S.D.)				
RFA	35.4 (15.3)	14.8 (11.1)**	12.5 (5.9)**	11.7 (12.3)**
BEC	21.3 (11.7)	14.3 (13.9)	9.7 (10.0)*	9.7 (9.0)*
p-value	0.011	0.907	0.371	0.638

* p -value (pre-post-treatment) <0.05 , ** p -value (pre-post-treatment) <0.001

S.D.=standard deviation, RFA=radiofrequency ablation, BEC=bipolar electrocautery

Table 3 Comparison of the peak nasal inspiratory flow, inferior turbinate grading, Epworth sleepiness scale and total functional outcome of sleep questionnaire at baseline, 1, 3 and 6 months after treatment

Parameters	Pre-treatment	1 month	3 months	6 months
PNIF (L/min), mean (S.D.)				
RFA	101.6 (34.0)	131.9 (25.6)*	142.1 (29.9)*	142.1 (31.2)*
BEC	107.1 (27.4)	127.1 (34.1)	133.2 (36.5)*	143.7 (37.5)*
p-value	0.641	0.678	0.485	0.905
Inferior turbinate grading, median (IQR)				
RFA	3.0 (3.0, 3.0)	2.0 (1.0, 2.0)**	2.0 (1.0, 2.0)**	1.0 (1.0, 2.0)**
BEC	3.0 (2.0, 3.0)	2.0 (1.0, 2.0)**	1.0 (1.0, 1.0)**	1.0 (1.0, 1.0)**
p-value	0.428	1.000	0.109	0.134
ESS, median (IQR)				
RFA	10.0 (7.5, 13.8)	6.5 (3.5, 7.0)*	6.0 (3.5, 6.5)**	5.0 (3.0, 7.5)*
BEC	9.5 (7.2, 13.0)	8.5 (4.4, 9.8)	6.0 (3.0, 9.0)	5.5 (3.2, 7.0)*
p-value	0.854	0.239	0.559	0.732
Total FOSQ, median (IQR)				
RFA	89.0 (56.2, 95.2)	102.0 (88.5, 111.8)	101.0 (73.0, 105.0)	96.5 (78.2, 102.0)
BEC	84.5 (80.5, 101.8)	85.5 (71.5, 109.5)	95 (91.0, 106.0)	96.5 (88.0, 102.0)
p-value	0.679	0.290	1.000	1.000

* p -value (pre-post-treatment) <0.05 , ** p -value (pre-post-treatment) <0.001

S.D.=standard deviation, IQR=interquartile range, RFA=radiofrequency ablation, BEC=bipolar electrocautery, PNIF=peak nasal inspiratory flow, ESS=Epworth sleepiness scale, FOSQ=functional outcome of sleep questionnaire

Table 4 Comparison of the compliance, attitude and ease of use of continuous positive airway pressure at baseline, 1, 3 and 6 months after treatment

Parameters	Pre-treatment	1 month	3 months	6 months
CPAP compliance, mean (S.D.)				
RFA	81.4 (21.7)	92.6 (8.1)	82.9 (24.0)	88.9 (15.3)
BEC	66.6 (29.2)	80.1 (29.8)	87.1 (24.0)*	88.4 (18.2)*
p-value	0.140	0.143	0.646	0.938
CPAP attitude, mean (S.D.)				
RFA	1.7 (2.8)	1.4 (2.3)	1.0 (1.3)	0.5 (0.9)
BEC	3.4 (4.0)	2.9 (2.7)	1.4 (2.3)	1.1 (1.8)*
p-value	0.205	0.150	0.542	0.271
Ease to use, mean (S.D.)				
RFA	2.4 (2.6)	2.0 (2.3)	1.5 (1.9)	0.9 (1.3)*
BEC	2.0 (2.7)	1.7 (2.2)	0.9 (1.1)	0.6 (1.1)
p-value	0.693	0.752	0.309	0.518

*p-value (pre-post-treatment) <0.05

S.D.=standard deviation, CPAP=continuous positive airway pressure, RFA=radiofrequency ablation, BEC=bipolar electrocautery

In the BEC group, there was a significant improvement in the CPAP compliance at 3 and 6 months. In contrast, the compliance did not change in the RFA group at before and six months postoperation. There were no statistically significant differences in the attitude and ease of CPAP use at 1 and 3 months in both groups. However, at 6 months postoperation, the attitude significantly improved in BEC (p-value=0.046) and the ease of use was better in the RFA group (p-value=0.047) (Table 4). Regarding immediate postoperative pain, the scores were higher in the RFA group than in the BEC group. The 2-week pain scores decreased without a significant difference between the groups. Moreover, the rescue medication was taken without differences as well. There were no complications in either group.

Discussion

Although CPAP is currently a highly effective treatment for OSA, patient compliance is not satisfactory and remains a difficult issue. Approximately half of the patients had not accepted it or had abandoned its use.²⁷ Moreover, up to two-thirds of the OSA patients did not

use a CPAP machine in the long-term follow-up.²⁸ Nasal obstruction is the main symptom complained about during CPAP therapy. It is typically caused by inferior turbinate hypertrophy and eventually leads to CPAP intolerance. In this study, we assessed nasal obstruction both pre-operatively and postoperatively at 1, 3 and 6 months. Both the BEC and RFA groups exhibited significant decreases in nasal obstruction at 1, 3 and 6 months postoperation; however, there is not different between the two groups. At 6 months postoperation, this symptom improved by 83.4% in the RFA group compared with 64.2% in the BEC group. Our results are consistent with those of a previous study that reported 80.0%–100.0%^{29,30} and approximately 90.0% were able to stop medications for nasal obstruction after RFA treatment.^{31–39} In contrast, Kilavuz et al.⁴⁰ showed that the BEC was more effective than the RFA at 8 weeks postoperation; however, the previous study used an electrocautery energy twice as high as that in our study. Moreover, the total nasal symptoms decreased in both groups at 1, 3 and 6 months. At 6 months postoperation, the symptoms improved significantly by 75.7% and 40.6% in the RFA and BEC groups, respectively. In this

study, the reduction in other nasal symptoms, including rhinorrhoea, sneezing, coughing, itchy nose and postnasal drip, were found more in the RFA group than in the BEC group, as in a previous study by Banhiran et al.³⁸ This might be explained by the energy which ablated the nerves and ceruminous glands.

In both groups, the inferior turbinate was significantly reduced in size, and the nasal airflow improved at 6 months postoperation. Interestingly, the CPAP compliance obviously improved in the BEC group after 3 months post-surgery. Contrarily, in the RFA group, the CPAP compliance did not significantly change. This could be explained by the fact that the baseline compliance was higher in the RFA group. Nevertheless, there were many factors that could have interfered in the use of CPAP, such as the use of a high CPAP pressure, dry throat, mask phobia, discomfort of equipment or poor attitude. However, in this study, the attitude towards and ease of CPAP were rather good at before and after treatment in both groups. Since the patients received more CPAP usage, their daytime sleepiness evaluation via ESS was significantly improved at 6 months postoperation in both groups. In addition, the scores of FOSQ tended to improve in both groups. In contrast, a study on the overall quality of life in patients with chronic rhinitis, refractory to medication and who underwent inferior turbinate reduction, revealed a significant improvement in all dimensions by the 8th week after RFA treatment.³⁸

The previous study showed that postoperative pain was lower with the RFA because of the lower energy. In contrast, our study showed no differences in the postoperative pain between the RFA and BEC groups. Both surgical techniques were minimally invasive under local anaesthesia, with mild postoperative pain and no serious complications. Their mechanisms involved forming a scar in the submucosal layer of the inferior turbinate without damaging the mucociliary function.

The advantage of this study is that the surgical procedures were performed by a single otolaryngologist. The skill of the physician seems to play a dominant role in the surgical outcome. Moreover, there have not yet been any studies comparing both surgical techniques in OSA patients using CPAP therapy. The limitation of the present study is that it was a short-term study with a small sample size. To improve this limitation, the authors will continue to follow the participants in the long term to evaluate the recurrence of nasal symptoms and its relationship with CPAP compliance. However, the present study confirmed that the effectiveness of both techniques was similar and satisfied the relief of nasal obstruction, improvement of CPAP compliance, and decrease of daytime sleepiness. Nowadays, electrocautery equipment is a basic inexpensive instrument that is more widely used in many hospitals than the radiofrequency equipment. Thus, it can be used as an alternative option in the treatment of nasal obstruction, especially in OSA patients using CPAP.

Conclusion

Both RFA and BEC have the ability to relieve nasal obstruction in OSA patients who use CPAP, which help improve CPAP compliance and relieve daytime sleepiness.

Acknowledgement

The authors would like to thank the Faculty of Medicine, Prince of Songkla University for funding and Miss Nannapat Pruphetkaew for her assistant in data analysis.

Funding sources

This work was supported by the Medical Research Council (grant number 59-195-13-1)

Conflict of interest

None declared

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